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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,965	11/14/2003	Charles H. Pugsley	06530.0288-01	7789

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EXAMINER	
KOHARSKI, CHRISTOPHER	

ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/706,965	PUGSLEY ET AL.	
	Examiner	Art Unit	
	Christopher D. Koharski	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions/Response to Arguments

Applicant's election with traverse of Group I in the reply filed on 4/21/2006 is acknowledged. The traversal is on the ground(s) that the subject matter has already been examined by the first examiner is persuasive because the first examiner has examined the subject on behalf of the office. However, the examiner still believes the restriction is still proper, the test for restrictable subject matter is a two-part test of which the difference in the claimed subject matter between groups I and II (apparatus and process) is proper.

Therefore, the requirement is withdrawn and currently claims 1-36 are pending for examination.

Response to Amendment

Examiner acknowledges amended claims 1, 2, 6, 15, and 24 and the cancellation of 4 and 5. Examiner acknowledges the amendment to the specification to correct the minor informality.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 - 4, 7 - 16, and 18 - 21 are rejected under 35 U.S.C 103(a) as being unpatentable over Binette et al. ('428). Binette et al. meets the claim limitations (as

described below) as described above except for the area being less than the surface area of the first surface.

Binette et al. discloses in Figure 3, a tissue patch (10) comprising a substrate (12), a tissue implant (11) attached to the substrate (12), and a protective liner (16) covering at least a portion of the tissue implant (11), wherein the tissue implant (11) is placed on a surface of the substrate (12), wherein the tissue implant (11) is embedded in the substrate (12) in the form of a cellular suspension (col. 2, lines 57 - 58), wherein the substrate (12) has a fjrst surface (14) for receiving the tissue implant (11) and a second surface (20) opposite to the first surface (14) for facing the lumen of the alimentary tract, wherein an adhesive material holds the patch proximate the lesion (col. 17, lines 18 - 23)', wherein the adhesive material includes cyanoacrylate (col. 17, lines 24 - 25)', wherein the protective liner (16) is attached to the substrate (12) via an adhesive material (col. 16, lines 40 - 44), wherein the protective liner (16) is removably attached to at least one of the substrate (12) and the tissue implant (11)., wherein the protective liner (16) is configured to be peeled away from at least one of the substrate (12) and the tissue implant (11), wherein the protective liner (16) is removably attached to the substrate (12)., wherein the substrate (12) is a bio-absorbable gel (col. 3, lines 65- 66)', wherein the substrate (12) includes bio-absorbable material having a predetermined thickness designed to last for a predetermined time period required for healing of the lesion so as to protect the tissue implant (11) from conditions in the alimentary tract (col. 7, lines 10 -11), wherein the substrate (12) includes a therapeutic

agent, such as antibiotics (col. 8, lines 44 - 45, lines 50 - 52), wherein the patch (10) is configured to be delivered endoluminally; wherein the patch (10) is configured to be folded into a contracted state during deliver into the lesion, wherein the patch (10) is capable of expanding upon deployment into the lesion, and wherein the patch (10) is configured to be rolled into a cylindrical shape.

In cases like the present, where patentability is said to be based upon particular chosen dimensions or upon another variable recited within the claims (area difference between the substrate and implant), applicant must show that the chosen dimensions are critical. As such, the claimed dimensions appear to be an obvious matter of engineering design choice and thus, while being a difference, there is no specific criticality in the claims or in the disclosure and the element does not serve in any way to patentably distinguish the claimed invention from the applied prior art. In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990); In re Kuhle, 526 F2d. 553, 555, 188 USPQ 7, 9 (CCPA 1975).

Claim Rejections - 35 USC § 103

Claims 17 and 22 - 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Binette et al. in view of Naimark et al. ('431). Binette et al. disclose the invention substantially as claimed in claims 1 - 4, 7 - 16, and 18 - 21, except for a therapeutic agent that is layered in a predetermined depth within the substrate so that the therapeutic agent activates at a predetermined time; wherein the tissue implant is a genetically engineered tissue; wherein a carrier is attached to the substrate, and wherein the carrier is configured to be peeled away from the substrate.

However, Naimark et al. disclose a therapeutic agent that is layered in a predetermined depth within the substrate so that the therapeutic agent activates at a predetermined time (col. 16, lines 60 - 66), wherein the tissue implant is a genetically engineered tissue (col. 14, lines 40 - 46), wherein a carrier is attached to the substrate (col. 15, lines 52 - 53), and wherein the carrier is configured to be peeled away from the substrate (col. 15, lines 27 - 28). Binette et al. and Naimark et al. are analogous ad because they are from the same field of endeavor.

At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the tissue patch of Binette et al. in view of Naimark et al. to include a therapeutic agent that is layered in a predetermined depth within the substrate so that the therapeutic agent activates at a predetermined time for the purpose of controlling the rate of delivering the therapeutic agent to the body tissue, to include a tissue implant that is genetically engineered for the purpose of delivering proteins of interest to the target site; to include a carrier that is attached to the substrate for the purpose of holding the tissue implant, and to include a carrier that is configured to be peeled away from the substrate for the purpose of revealing the tissue implant to the body tissue surface being treated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 3, 15, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke et al. (5,344,454).

Regarding claims 1, 2, 3, 15, 16, 18, 19 and 21, Clarke et al. discloses a tissue implant device that is capable of being placed in the lumen of the alimentary tract with a substrate, tissue implant, protective liner, and a relative size difference (Figures 2, 3, 4) between the tissue implant and the substrate (membrane). The tissue implant can be a suspension of cells and can be placed into the membrane and is capable of being folder and placed into a tissue area (Figure 7).

Claim Rejections - 35 USC § 103

Claims 25- 36 are rejected under 35 U.S.C 103(a) as being unpatentable over Binette et al. in view of Naimark et al. in further view of Podolsky (WO 02/085402). The modified Binette et al. meets the claim limitations as described above except for some of the specific steps of placing the tissue patch in the lesion.

However, Podolsky teaches methods and compositions for treating oral and esophageal lesions.

Regarding claims 25-36, Binette et al. in view of Naimark et al. in further view of Podolsky teaches putting in a three layer treating agent that in placed into the throat of a patient and using the devices of Binette et al. and Niamark et al. (page 13 and 14, Podolsky) to insert the device and remove a liner to attached and release drug compound into the patient at the lesion site (page 1). At the time of the invention, it would have been obvious to use the steps of Podolsky with the systems of Binnette et al. and Naimark et al. because optimal achievement or lesion treatment can be

achieved. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Podolsky.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/14/06

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